

EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

EXPERT REPORT OF
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March 30, 2017

I. Professional Qualifications

My education and training are in medicine (internal medicine and pulmonary disease) and public health, specifically the discipline of epidemiology (see Exhibit A – curriculum vitae). I received an A.B. degree from Harvard College in Chemistry and Physics and then received my M.D. degree from the University of Rochester School of Medicine and Dentistry. My training after medical school included completion of three years of training in the specialty of Internal Medicine and a three-year fellowship at Harvard Medical School that included training in the subspecialty of Pulmonary Medicine. I am Board certified in both, although I have not engaged in the clinical practice of medicine since 1994, when I left my position at the University of New Mexico for the then Johns Hopkins School of Hygiene and Public Health (now the Johns Hopkins Bloomberg School of Public Health). During my fellowship in clinical epidemiology at the Channing Laboratory of Harvard Medical School, I also received a master's degree in epidemiology from the Harvard School of Public Health.

Of relevance to this report, I served in the US Army from 1971-1973 as a physician. This service followed my internship in Internal Medicine at the University of Kentucky (1970-1971). Based on a critical need at the time, I received on-the-job training in anesthesiology and spent the two years of my military service as an anesthesiologist at Gorgas Hospital in the then Panama Canal Zone. The Hospital was a large facility providing care primarily for military personnel and their families, and Canal Zone employees and dependents. On a day-to-day basis, anesthesia for patients in four to six operating rooms was largely administered by nurse anesthetists under the supervision of a fully trained anesthesiologist and myself. Beyond this supervisory role, I handled many cases. Consequently, I gained extensive first-hand experience with general operating room procedures, as then practiced, covering a wide range of surgical procedures including hip replacement.

Subsequent to my fellowship training at Harvard as documented on my curriculum vitae, I have had positions at three academic institutions: the University of New Mexico School of Medicine in Albuquerque, New Mexico (1978-1994); the Johns Hopkins Bloomberg School of Public Health (1994-2008); and the University of Southern California (2008-present). At each of these institutions, I have held leadership positions including Chief of the Pulmonary and Critical Care Division of the Department of Medicine at the University of New Mexico; Chair of the Department of Epidemiology, Co-Director of the Risk Sciences and Public Policy Institute (which I co-founded), and Co-Director of the Institute for Global Tobacco Control (which I founded) of the Johns Hopkins Bloomberg School of Public Health; and Chair of the Department of Preventive Medicine of the Keck School of Medicine of USC and founding Director of the Institute for Global Health of the University of Southern California. In these positions, my responsibilities have included a mix of administration, research, education and training, and clinical practice (while at the University of New Mexico).

In general, my research activities have been centered on the health consequences of inhaled agents, such as tobacco smoke, outdoor and indoor air pollution, and radon, but also extended to the causes of cancer and the determinants of outcome for those with cancer, to cardiovascular disease and sleep-disordered breathing, and to obesity. My curriculum vitae lists my specific publications, which now number over 360 peer-reviewed research papers, approximately 400 additional publications, and 28 books and monographs.

Much of my research has addressed exposure to airborne particulate matter and the health consequences of such exposures, including the particulate progeny of radon, secondhand tobacco smoke, and particles in outdoor air. In this research, I have been involved in leading teams that have measured particle concentrations in outdoor and indoor air, and collected particles for toxicological assays. I have been involved broadly in policy issues related to indoor air quality and particulate matter, including serving on Committee 62 of the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE), which addresses ventilation of indoor spaces. For the National Research Council, I chaired the Committee on Research Priorities for Airborne Particulate Matter, the Committee on Comparative Dosimetry of Radon in Homes and Mines, and the Committee to Develop a Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials—all concerned with particles. Finally, while I was at Johns Hopkins, I was Principal Investigator for an Environmental Protection Agency funded Center for research on particulate matter.

In addition, since the 1980s, I have been involved in numerous expert panels, reports, and other activities that have involved the synthesis and evaluation of evidence for causal inference and for risk assessment, a process that typically begins with an evaluation of the evidence for existence of a hazard. Most relevant, I have been involved with the US Surgeon Generals' reports on smoking and health since 1984 in capacities including

author, consulting editor, and senior scientific editor. These reports provide authoritative determinations on the causation of disease and other adverse effects of smoking using a framework for inference that originated with the landmark 1964 report. This report established a model approach for synthesizing evidence for the purpose of reaching causal conclusions related to smoking with significant policy and public health impact. Subsequent reports have had broad impact, such as the 1986 report of Surgeon General Koop on involuntary smoke, which catalyzed the movement for clean indoor air with its conclusion that involuntary smoking caused lung cancer in never smokers. I was a Consulting Scientific Editor for this report.

As Senior Scientific Editor for the 2004 report, I led the updating of this approach to evidence evaluation and the introduction of standard language to describe the strength of evidence for causation. Across multiple reports, I have participated in the evaluation of evidence for causation as author and editor, reaching new causal conclusions in several reports, including the 1986 report (e.g., involuntary smoking causes lung cancer), the 2004 report (e.g., active smoking causes cervical cancer and cataract), and the 2014 report (e.g., active smoking causes cancer of the liver and involuntary smoking causes stroke). I was Senior Scientific Editor for both the 2004 and 2014 reports.

As a member and chair of the Clean Air Scientific Advisory Committee (CASAC) of the US Environmental Protection Agency, I provided guidance on revisions to the Agency's process for evaluating evidence and inferring causation for the major "criteria" air pollutants, such as airborne particulate matter. As chair of several committees of the National Academies of Sciences, Engineering, and Medicine, I have provided guidance on revisions to the Agency's processes for chemical risk assessment in its Integrated Risk Information System (IRIS) Program. These revisions have included introduction of formal systematic review processes and uniform approaches for assessing strength of evidence.

As an internist and pulmonary physician, I provided care for numerous patients with infectious diseases, some complicating surgery. While at Johns Hopkins, the Department of Epidemiology, which I chaired, was one of the largest academic programs in infectious disease epidemiology, providing an opportunity for me to learn much about this area from my colleagues.

II. Statement of the Question

Judgments concerning causation are made for the purposes of public health protection and health promotion at the population level. Evidence related to the causation of disease (or possibly to a benefit to health) at the population level is considered and a determination made as to whether the evidence supports the inference of a causal relationship between an agent and a particular health outcome. Such general determinations support various types of interventions intended to improve the health of

populations. Examples abound—air quality regulation, tobacco control at local, state and federal levels, and regulations covering exposures in workplaces. The determination in the 1964 Report of the Advisory Committee to the Surgeon General—that smoking causes lung cancer (in men)—is a landmark example, both for the methods used to evaluate the evidence and for the impact of the conclusion.

Distinct from population or general causation, judgments as to causation of disease in specific individuals are also made for a variety of purposes. These determinations address the question as to whether one (or more) agents contributed to the causation of disease in a specific person. The judgment is typically couched in terms of a probability statement, e.g., there is a 60 percent chance that a factor caused a particular disease in a particular person or the probability might be summarized as to whether it is more likely than not that a particular agent was causal for the individual in question.

This report addresses the topic of general causation in regard to the Bair Hugger forced-air warming devices (referred to hereafter as the Bair Hugger device), considering the full range of available and relevant evidence. The question addressed is whether use of a Bair Hugger device during hip and knee joint replacement surgeries increases risk for deep joint infections. “Risk” as used here means that the probability of deep joint infection is increased compared to what that probability would have been, absent the utilization of the Bair Hugger device during hip and knee arthroplasties. In this report, I refer to this theoretical comparison scenario of no exposure to the presence of the Bair Hugger device during surgery as the *counterfactual*. I propose that the appropriate counterfactual is either no specific warming device or the use of a warming device that does not involve forced-air, the actual alternatives in practice.

Concepts of Causation

Causal Criteria or Guidelines: The present scientific and methodological approaches used for causal inference have their origins in discussions started in the 1950s as observational epidemiological evidence emerged on the causes of “chronic diseases” (primarily cancer, cardiovascular disease, and chronic respiratory disease) related to smoking and other environmental factors. Unlike infectious diseases, for which there were necessary causal agents—i.e., the particular infecting microbes—chronic disease or non-communicable diseases generally had multiple risk factors and no one cause was necessary as for infectious diseases. Criteria (the Henle-Koch postulates) for determining if an infectious agent caused a disease in humans were proposed in the later years of the 19th century as the role of infectious organisms in human disease was established.

The Henle-Koch postulates had no direct extension to non-communicable diseases. For clear ethical and practical reasons, experiments could not be carried out to prove that cigarette smoking or other agents had adverse consequences in people. Additionally, the results of the observational studies were potentially subject to bias, including

confounding (the mixture of the effect of another factor, the confounder, with the effect of the exposure of interest), selection bias (the distortion of the true association by the way that participants are selected into study populations), and information bias (errors in the information included in a study).

The approach developed for evaluation of evidence used in the 1964 Surgeon General's report (U.S. Department of Health Education and Welfare, 1964) and in many subsequent authoritative reports, including those of the Surgeon General on smoking and health (U.S. Department of Health and Human Services, 2014), was intended to give appropriate consideration to these issues in interpreting the critical public health evidence. Consequently, systems were developed for comprehensively gathering evidence from individual epidemiological studies, assessing the potential for bias in the individual studies and the collective body of literature, and synthesizing the evidence from the studies to determine if the findings, along with evidence from other types of investigation (e.g., laboratory studies), were sufficient to support a causal conclusion: i.e., that the observed association reflected a causal process and not bias or the play of chance (Glass et al., 2013).

The landmark 1964 report of the US Surgeon General on smoking and health (U.S. Department of Health Education and Welfare, 1964) is widely regarded as providing a model approach for the systematic review of evidence in order to determine if the association between an "exposure" or "risk factor" and some health outcome(s) is causal. Key features of the approach used to develop the report and conclude that smoking causes lung cancer included:

- a. The evidence then available was systematically assembled and reviewed for potential methodological concerns (e.g., confounding) and the implications of such concerns for study interpretation;
- b. Multiple lines of evidence were considered including the nature and components of cigarette smoke, findings of toxicological research, epidemiological research, and data showing coherence with the hypothesis that smoking causes lung cancer, such as parallel trends of smoking and lung cancer rates in the population;
- c. Development of a pragmatic definition of cause and of guidelines or criteria for evaluating evidence for causation (Table 1). Similar guidelines were proposed at about the same time by Sir Austin Bradford Hill in the United Kingdom. Of these guidelines, only temporality (i.e., cause precedes effect) must be met, but the others are critical in bolstering the case for causation and are fundamental to the weight-of-evidence approach used to evaluate the totality of the evidence available. The guidelines are not used as a checklist and all need not be met to infer causality;
- d. Narrative analysis of the evidence using the guidelines to demonstrate in a transparent fashion the basis for the causal determination.

Sufficient Component Cause Framework: In considering the evidence collected for this report and the nature of the injury related to the Bair Hugger device, the sufficient-component-cause model or framework is relevant and useful. The framework provides insight into how the Bair Hugger device could increase risk for infection, when by definition an infectious organism is requisite for the occurrence of a deep joint infection. This framework considers sets of actions, events, or states of nature that together lead to the outcome under consideration. The model provides a way to account for how multiple factors combine to result in disease in an individual or population. In epidemiology, the component cause model put forward by Kenneth Rothman in a 1976 publication (Rothman, 1976) has clear applicability to considering the role of the Bair Hugger device as a causal factor. This model has broad utilization, being invoked, for example, in a recent report from a committee of the National Academies of Sciences, Engineering, and Medicine that I chaired. This report from the Committee on Using 21st Century Science to Improve Risk-Related Evaluations used the sufficient component cause framework to characterize how pathways of injury by chemicals increase risk for disease (National Academies of Sciences Engineering and Medicine, 2017).

In considering causation, causal factors are classified as to whether they are necessary or sufficient. A cause that is *sufficient* can cause disease on its own but it may not be necessary. For infectious diseases, the responsible microbial organism is necessary, but not sufficient for many infectious organisms. For example, most people who are infected with *Mycobacterium tuberculosis*, the organism responsible for clinical tuberculosis, do not develop clinical disease; the immune system is able to control the infection such that disease does not occur. For lung cancer, smoking is presently the cause of most cases (about 85%) in the United States, but smoking is not sufficient (all smokers do not develop lung cancer) nor necessary (lung cancer occurs in people who have never smoked).

In the component cause model, causal complexes that are sufficient, i.e., able to cause the outcome of concern, are represented by pies (Figure 1) with each slice being a single component of the pie, i.e., an insufficient component by itself unless the pie has only one component (Rothman and Greenland, 2005). The figure depicts three causes (I-III), each having multiple components or slices. When a cause is complete (i.e., each of its components is present), then the outcome will occur. The importance of a cause in a particular population is determined by its prevalence; different populations may have different distributions of causes, e.g., younger versus older patients or a community hospital versus a referral center. The model usefully captures multicausality in the existence of several causal pies having multiple and differing components, the dependence of the strength of component causes on the prevalence of the complementary component causes, and the interaction between component causes.

For infectious diseases by definition, the infectious organism is necessary, corresponding to component A in the example of Figure 1, which is present in causes I, II, and III.

Thus, if a necessary component cause can be eliminated, any occurrence of the outcome can be avoided. If a component is present in only one cause, the removal of that component leaves the other causes as pathways to causation. With removal of cause J, for example, cause III is eliminated but causes I and II persist. This model has ready extension to considering the role of the Bair Hugger device in causing deep joint infections, as it captures the necessary presence of the infecting agent and how additional factors contribute to risk (Figure 2).

Figure 1: Hypothetical Example of Three Sufficient Causes of Disease From: Rothman KJ, Greenland S. Causation and causal inference in epidemiology. Am J Public Health. 2005; 95 Suppl 1:S144-50.

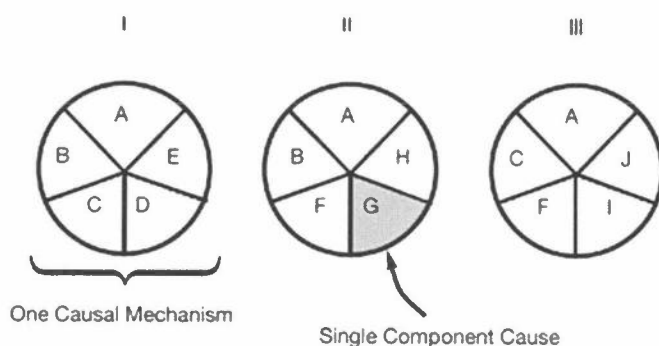


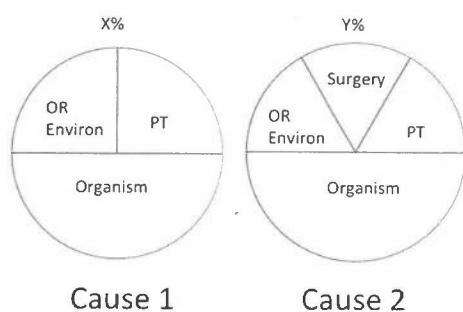
Figure 2 provides a hypothetical extension of the sufficient component cause model to deep joint infection and the role of the Bair Hugger device. It has two panels, portraying two different causal situations: the first, absent the presence of a Bair Hugger device, has two causes, each with several components; and the second, which has three causes with the addition of a cause with the Bair Hugger device as a component. Because the infecting organism is necessary, it is present in all of the causes in both panels. In the first panel (A), the first cause (Cause 1) has three general components—infected organism, operating room environment, and patient; the second (Cause 2) has four components—infected organism, operating room environment, patient, and surgeon. I use the terms “operating room environment,” “patient,” and “surgeon” in a general sense to refer to any characteristics/correlates that may influence the risk of infection. The “operating room environment” could encompass a broad range of features related to design, including air handling, operational aspects, and cleaning. Patient susceptibility factors are of evident importance and might include underlying health and immune status, smoking status, age, and relative body weight (body mass index or BMI). There are diverse pathways by which a surgeon might affect risk for infection: technique and procedure length or colonization with methicillin-resistant *Staphylococcus aureus* (MRSA).

The second panel (B) includes a third cause with four components—infected organism, operating room environment, patient, and Bair Hugger device. The third cause includes

the Bair Hugger device, along with patient characteristics and the operating room environment. Comparison of the two panels in this hypothetical shows how the presence of the Bair Hugger device increases risk for deep joint infection, adding an additional cause to the two causes already present. The increment could be considered in absolute or relative terms: i.e., the prevalence of the additional, third cause with the Bair Hugger device or the relative increment in disease comparing the overall prevalence of the three causes in the second panel to that of the two causes in the first panel. The addition of the third circle shows how the use of the Bair Hugger device increases risk for disease; assuming the frequencies of the other two causes remain unchanged, the use of the Bair Hugger device adds an additional cause and hence more deep joint infection in comparison to the (counterfactual) scenario of only two causes. The magnitude of the increase would depend on the prevalence of the cause with the Bair Hugger device.

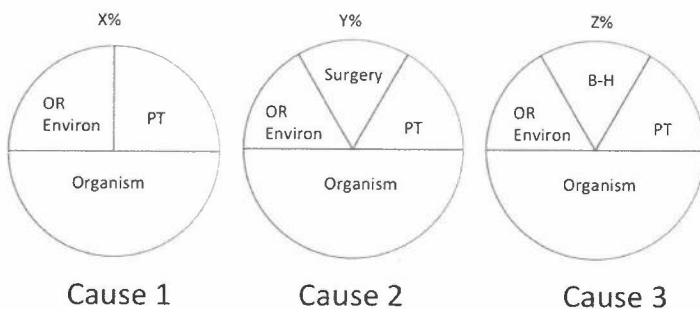
Figure 2: Adaptation of Sufficient Component Cause Model to Deep Joint Infection Risk

A: Causal Mechanisms for Deep Joint Infection without Bair-Hugger Devices



These causal pies are hypothetical and are not drawn to scale.
OR Environ = Operating Room Environment; PT = Patient;
Surgery = Surgical procedure factors

B: Causal Mechanisms for Deep Joint Infection with Bair-Hugger Devices



These causal pies are hypothetical and are not drawn to scale.
OR Environ = Operating Room Environment; PT = Patient; B-H = Bair Hugger Device
Surgery = Surgical procedure factors

With regard to the question of general causation, evidence is considered as to whether evidence supports the existence of Cause 3 in Figure 2. The model acknowledges the necessity of having an infectious organism and the contributions of patient susceptibility and other factors. It also illustrates how the existence of Cause 3 causes deep joint infections, beyond what would occur if only Causes 1 and 2 are present. Figure 2 also shows that the degree to which Cause 3 increases risk depends on the prevalence of other factors, such that the risk for deep joint infections associated with use of the Bair Hugger device could vary across institutions. Below, I review the evidence supporting the existence of a causal mechanism involving the Bair Hugger device.

III. Review of the Evidence

In writing this report, I have relied on studies from two sources: literature provided by Ciresi Conlin LLP and by literature searches conducted at USC using PubMed and the following search terms: “trends in surgical wound infections,” “National AND trends AND (surgical AND wound AND infection),” “Trends AND (surgical AND wound AND infection),” “Trends AND (surgical AND nosocomial AND infection),” “Trends AND (surgical AND wound AND infection) AND device,” “(Patient AND warming AND device) AND (surgical AND wound AND infection),” “(Patient AND warming) AND (surgical AND wound AND infection),” “(Patient AND warming AND device) AND (operating AND room),” “(Patient AND warming) AND (operating AND room),” “(Patient AND warming) AND (nosocomial AND infection),” “(Patient AND warming) AND (surgical AND site AND infection),” “microbial AND contamination AND operating AND room,” “surface AND contamination AND (operating AND room),” “surface AND contamination AND (operating AND room).” The references of the main publications were also searched for additional relevant citations. I reviewed reports prepared by two of Plaintiffs’ experts: Drs. William Jarvis and Said Elghobashi. Finally, I considered all the documents referenced in Exhibits B and C of this report.

Evidence Synthesis and Findings on Causation

The Range of Evidence Available: Judgments on causation of an adverse effect of an agent, whether an environmental exposure, a pharmaceutical, or a device, like the Bair Hugger device, are made on the basis of all relevant evidence, whether direct or indirect. In schemas of evidence hierarchy, randomized clinical trials are generally given the most credence, but such trials are carried out to test for efficacy of a device or therapeutic agent or the comparative efficacy or equivalence of two devices or agents. They are not generally carried out to document adverse consequences or to make a comparison of the risks of two different devices or therapeutic agents. Thus, there has not yet been a randomized clinical trial to address the potential infection risk associated with the Bair Hugger device (i.e., a trial comparing the Bair Hugger to some other warming modality). In fact, such trials would not be readily feasible in practice because of the low incidence of deep joint infections; informative sample sizes would need to be very large; and such

studies have not been reported to date. Results of a randomized controlled trial evaluating the efficacy of a device that reduces the concentration of colony-forming units (CFUs) at surgical sites were recently reported and are discussed further below (Darouiche et al., 2017).

Observational epidemiological studies have been the mainstay for investigating the causes of disease in human populations. Observational means that the study addresses the consequences of exposures as they take place in the world and that the exposures are not assigned by the researchers as in a randomized clinical trial or other type of experiment. Rather, investigators study the consequences of factors affecting health as people are exposed to those factors based on “real world” determinants. For example, observational designs were used in linking cigarette smoking to lung cancer, as some people were either current or former smokers and others had never smoked. Two basic designs were used: the case-control study comparing the smoking histories of people with lung cancer (cases) to those of similar people, but without lung cancer (controls); and the cohort study comparing the rate at which lung cancer develops in smokers over time to that in never or nonsmokers. The findings from such studies, interpreted in the context of other lines of evidence, supported the conclusion in 1964 by the Advisory Committee to the Surgeon General that smoking caused lung cancer (in men) (U.S. Department of Health Education and Welfare, 1964).

Only limited observational data are available on the potential infection risks from the Bair Hugger device, reflecting the way in which warming devices are typically purchased and used in hospitals, i.e., a hospital would generally use only a single type of warming device in its operating rooms so that comparison to another device cannot be readily made. The general research question on warming devices and infection risk has attracted limited attention to date.

On the assumption that hospitals use only a single type of warming device in operating rooms, investigation of infection risks associated with type of warming device could be carried out by classifying hospitals as to the type of warming device used and comparing deep joint infection rates for groups of hospitals classified by type of warming device used, taking other factors into account that could differ among hospitals. Such studies have not been done and would be difficult to carry out. Another approach would be to carry out a quasi-experimental study within one or more hospitals, monitoring the rate of deep joint infection over time with one device and then intentionally shifting, as abruptly as possible, to an alternative device. A change in the infection rate temporally linked to the change in device would indicate a beneficial or adverse effect of one device compared to the other. A study intentionally following this design has not been carried out, but studies have addressed changes in deep joint infection rates as changes have been made in warming equipment (discussed below).

Another line of evidence that has been evaluated is the characterization of time trends of rates of surgical site and deep joint infections. The hypothesis could be advanced that if Bair Hugger devices substantially increase deep joint infection rates, then time trends of rates of such infections should track with the timing of the introduction and utilization of the devices. This is an inherently flawed approach since it does not directly address the risks of the Bair Hugger device; the relevant data on trends are not readily available; and the consequences of other factors changing over time cannot be taken into account. The example of time trends of lung cancer in the United States illustrates the point: While incidence and mortality rates have been dropping in men for several decades because of lessening use, the risk of lung cancer in smokers has risen over this same time period (U.S. Department of Health and Human Services, 2014).

There is one directly relevant observational study in the peer-reviewed literature: the retrospective study carried out by McGovern et al. (McGovern et al., 2011). The study was based on comparing rates of deep joint infection in a hospital in the United Kingdom in two periods: one with the Bair Hugger device in use and one with conductive-fabric warming in use. Figure 7 in the publication describes the structure of the investigation: a period of exclusive use of the Bair Hugger device, a transition period, and then a period of exclusive use of conductive warming. Observation for surgical site infection, including deep joint infection, was standardized across the period of the study, but there were changes in both antibiotic prophylaxis and thromboprophylaxis. Logistic regression was used to estimate the incremental risk associated with having surgery while the Bair Hugger device was in use; the univariate estimate of the odds ratio was 3.8 and statistically significant.

This finding has been criticized as potentially reflecting confounding by the non-comparability of prophylactic antibiotic use and thromboprophylaxis in the two periods. Changes were made in both that overlapped with the different time periods described in Figure 7 of the paper. These arguments are the typical general claims made by those seeking alternative explanations for an association, and reach back to the strategies employed for decades by the tobacco industry (Proctor, 2012; Samet and Burke, 2001).

The deposition testimony of the authors of the McGovern paper addresses the issue of confounding. In an extended data set, Professor Nachtsheim compares infection rates under the two antibiotic regimes during a period when the Bair Hugger device was in use. There is no significant difference in the infection rates, indicating that one key requirement for confounding is not met: an association of the potential confounder (antibiotic use protocol) with the outcome (deep joint infection). Drs. McGovern and Reed cite additional evidence against confounding, including peer-reviewed studies indicating that different thromboprophylaxis protocols do not significantly impact deep joint infection rates (Jensen et al., 2010; Jameson et al., 2012). The authors also explain that additional data collected after publication of the McGovern study continued to

demonstrate a relative risk ratio very similar to the 3.8 odds ratio reported in the published study.

A more general argument against confounding can also be made. In setting aside whether the antibiotics and/or thromboprophylaxis were truly “confounding,” the magnitude of the association (3.8 odds ratio) reported by McGovern et al. deserves consideration. For the sole explanation to lie with confounding, there would need to be sufficient positive confounding by changes in antibiotic use and/or thromboprophylaxis to explain the association fully. Such confounding is not only unlikely, but it is not supported by the evidence considered above and as reviewed by Professor Nachtsheim and Drs. McGovern and Reed. Additionally, given that the change in the warming method was temporally abrupt, confounding by other, unidentified factors seems unlikely as well. For example, the mix of patients in the time periods compared would likely be unchanged, as would factors related to the operating staff and operating rooms. The 3.8 relative risk ratio is therefore not attributable to confounding.

Other studies have been construed as “negative” and indicating safety of forced-air warming with the Bair Hugger device. In a widely used definition of safety, Lowrance (Lowrance, 1976) proposed that “A thing is safe if its risks are judged to be acceptable.” This definition implies that risk can be estimated and then assessed for its acceptability. To conclude that there is no risk for deep joint infection associated with forced-air warming, an estimate of risk based on an appropriate counterfactual comparison is needed that is sufficiently precise to exclude risk levels considered unacceptable. In other words, the relative risk for deep joint infection associated with use of forced-air warming would need to be estimated along with 95% confidence intervals, as is the usual practice. The upper limit of the confidence interval would have to be below risk levels that are considered unacceptable, such as 1.5—the level at which risk is increased by 50%. To have such precision, sufficiently large studies would be needed and multiple studies would be needed to have sufficient confidence in the results. Such evidence does not exist.

Studies have been construed as indicating safety of the Bair Hugger device. However, considering the formulation of safety set out above, the studies provide findings seriously constrained by limited sample size without indicating that there is no risk with any degree of precision. Five studies are briefly described here.

1. Zink and Iaizzo (1993) assessed bacterial contamination using culture plates during simulated surgery with eight volunteers with a protocol that included two control hours and two hours with the Bair Hugger device operational. There was no significant difference in the number of bacterial colonies comparing the two periods.
2. Avidan and colleagues (1997) studied nine Bair Hugger devices and one additional device in use at their hospital. Beyond culturing the airstreams of the

devices, several extremely limited experiments were carried out. In one experiment involving only two devices, no organisms were cultured in the exhaust air from two devices that previously tested positive for internal contamination.

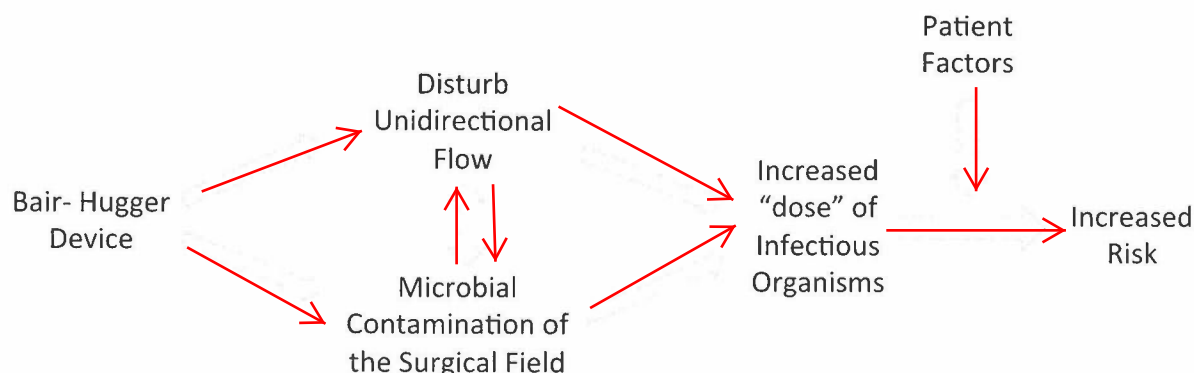
3. Huang et al. (2003) measured bacteria counts at several locations and the wound site in 16 abdominal vascular procedures during which a Bair Hugger device was used. Bacterial counts dropped across the procedure.
4. Moretti et al. (2009) followed a protocol similar to that used by Huang et al. for 30 surgeries, including 20 with a Bair Hugger device. The results showed an increase in counts compared to initial at-rest conditions and a comparison is not presented of the 20 procedures with warming versus the 10 without.
5. Sessler et al. (2011) carried out a simulation study of the consequences of forced-air warming with Bair Hugger devices on tracer smoke particle counts in two operating rooms with laminar flow in place. The investigators report no significant differences in particle counts, comparing baseline and operation of the Bair Hugger devices with and without warming of the air. Data provided in Figures 2 and 3 in the published paper show increases in particle counts with the Bair Hugger device in use, particularly for the Bair Hugger model 635. The small sample size limited statistical power.

These five studies share the problem of limited sample size and statistical power. Moreover, the interpretation of the evidence by the authors is largely based on not finding statistically significant differences in small data sets. Thus, the studies do not demonstrate the safety of the Bair Hugger device. Accordingly, in terms of the larger, collective body of evidence on risk for deep joint infection, these five studies are a limited and flawed component.

The Mechanisms by which the Bair Hugger Increases Risk for Deep Joint Infection:

Here, I give emphasis to the findings that address the processes by which the Bair Hugger device could increase risk for infection (Figure 3). There are two general documented mechanisms captured in Figure 3: disruption of protective unidirectional flow across the surgical field and an increased load of microorganisms in the air due to contamination of the forced-air warming device and turbulence-driven flow distributing contaminated skin flakes (squames) into the operative field. Both of these mechanisms lead to an increased number of CFUs delivered to the surgical site.

Figure 3: Mechanisms by which the Bair Hugger Device Increases Risk for Deep Joint Infection



Central to these mechanisms and risk for deep joint infection is the established relationship between the “dose” of CFUs and risk for surgical site and deep joint infection. With regard to infection risk, dose can be conceptualized as the cumulative number of CFUs that enters the surgical field, whether airborne, entering on instruments and other materials, or on the hands of surgical personnel. The dose would thus constitute the cumulative number of infectious organisms from these various routes. In Figure 3, the Bair Hugger device could increase the dose by increasing the number of airborne organisms deposited onto the surgical site or by contaminating instruments or surgical personnel as airborne CFUs settle onto these surfaces.

As reviewed by Dr. Jarvis, evidence suggests that only a small number of infectious organisms are needed to cause a deep joint infection to occur with knee and hip replacement, given the presence of a foreign material coated with a biofilm, which provides a site for growth that is not readily reached by antibiotics. Findings cited by Dr. Jarvis indicate that only a small number of organisms, possibly even a single organism, may be sufficient. A higher number of organisms reaching the implant increases the risk of infection. The randomized trial reported by Darouiche et al. (2017) further supports the concept of dose, as proposed, and the dependence of risk of deep joint infection on the number of organisms reaching the prosthesis. That study showed that reduction of CFUs reaching the surgical site with use of the Air Barrier System led to a lowering of the number of implant infections (four in the control and none in the intervention). Additionally, as noted by Dr. Jarvis, patient-associated factors are not directly causal, but can increase risk for infection as diagrammed in Figure 2.

Use of the Bair Hugger device in the operating room has two consequences that increase the dose of CFUs, and hence the risk of infection, delivered to the surgical field: disturbance of unidirectional flow across the site and an increase in microbial contamination in the operating room. A substantial literature supports both of these effects of the operation of the Bair Hugger device. With regard to disturbance of

unilateral flow, there are two lines of supporting evidence: empirical studies in operating rooms that document air flow patterns and computational fluid dynamic modeling (CFD). Plaintiffs' expert Dr. Elghobashi implemented a CFD model to describe how the operation of a forced-air warming device affects patterns of air movement within an operating room and the consequences for distribution of squames (human skin cells) during an operation—a patient undergoing knee surgery. The results of the simulation are clear, comparing the two cases—blower off and on: operation of a Bair Hugger device alters air flow and increases the numbers of squames reaching critical sites relevant to infection risk, including the surgical site and the side tables. Two studies document thermal gradients created by the Bair Hugger device that parallel the modeling of Dr. Elghobashi (Table 2).

The results of Dr. Elghobashi's modeling are paralleled by empirical studies using tracers in operating room settings (Table 3). Table 3 summarizes the results of four studies that used simulated surgical procedures to assess the impact of the operation of a Bair Hugger device versus a comparison condition on the concentration of an indicator of airborne contamination. A study by Stocks et al. (2010) supports the use of particle counts as an indicator of the potential concentration of CFUs. In this study, particle concentrations in various size bins were measured at the surgical site during 22 hip and knee procedures. The number of CFUs was also measured at the surgical site. The relationships of particle counts and several characteristics of the procedures and staff with CFUs was considered during 10-minute time blocks. Of the various particle size bins, concentration of particles 10 microns and greater was most strongly associated with CFU count, explaining 41% of the variance in CFU concentration. This finding supports the use of particle tracers and counts as a surrogate for CFUs.

A study by Legg et al. (2012) measured particle counts while the other three used tracers, including glycerol particles and detergent bubbles. All show substantial increases in concentrations/counts of the indicator, as acknowledged by 3M's 30(b)(6) witness. The report by McGovern et al. (McGovern et al., 2011) included an investigation of the effect of forced-air warming with a Bair Hugger device on disruption of unidirectional air flow using neutral-buoyancy bubbles as a marker. Two simulated procedures were included: hip replacement and a lumbar spinal procedure. The experiment provided strong evidence that use of forced-air warming, compared with conductive-fabric warming, increased bubble counts over the surgical site in both sets of simulations. The findings of Belani et al. (Belani et al., 2013) were similar.

In another simulation study, Legg et al. (2012) measured particle counts in different size ranges over the surgical site, comparing forced-air warming with conductive fabric warming and no warming. The findings showed increased particle counts in the three size bins considered versus the two comparison conditions. In a subsequent study, Legg et al. (2013) used 0.3 micron glycerol particles as the tracer and found a several thousand-fold increase in particle count associated with use of a Bair Hugger device.

The Bair Hugger device may also increase the dose of CFUs as a result of the contamination of the device by microbes and the distribution of microbes in the warmed air from the device. Evidence summarized by Dr. Jarvis supports each of these mechanisms by which the device could increase the dose of organisms delivered to the surgical site.

Findings on Causation: As noted, judgments as to causality are based on a review of the relevant lines of evidence and evaluation of the evidence within a framework for causal inference, e.g., that used in the Surgeon Generals' reports. These frameworks are not intended to be rigid and in using them, the scope and nature of the evidence available merits consideration. The relevant criteria include temporality, strength of association, consistency, and coherence. *Specificity* is not pertinent, as there are multiple factors associated with risk for deep joint infection following arthroplasty and an infectious organism is necessary. The critical and necessary requirement of *temporality* is inherently met because joint replacement and exposure to infectious organisms precede the occurrence of infection, often by months.

With regard to *strength of association*, the available observational evidence indicates a moderately strong association. The analysis reported by McGovern and colleagues documents a statistically significant association unlikely to be explained by confounding or other bias. The relative risk is estimated at 3.8. The studies summarized in Table 3 show that use of a Bair Hugger device substantially increases the concentration of various tracers over the surgical site, in fact by up to several orders of magnitude.

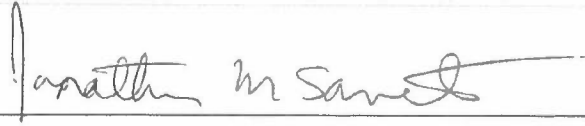
The guideline of *consistency* is generally applied as a consideration related to interpretation of findings of multiple observational studies and hence is not applicable to the single study by McGovern and colleagues. Here, I point to the consistency of the findings of studies addressing the effect of the Bair Hugger device on particle counts at the surgical site (see Table 3).

As discussed above, there is *coherence* across the streams of evidence supporting the model set out in Figure 3, which offers a well-supported picture of the mechanisms by which the Bair Hugger device increase risk for deep joint infection. There is a coherent body of evidence supporting both pathways. Through the pathways indicated in Figure 3, the Bair Hugger device increases the dose of microbes reaching the surgical site and an increase in this dose increases risk for deep joint infection. The study by McGovern and colleagues shows that the resulting increase in risk of deep joint infection is substantial. The evidence is thus consistent and coherent, and biological plausibility for the Bair Hugger device to increase risk for deep joint infection is well established.

In my judgment, the full body of evidence is sufficient to conclude that the Bair Hugger device causally increases risk for deep joint infection. There is sufficient consistency among the findings of the individual studies, the evidence is coherent, biological

plausibility is evident, and temporality is satisfied. As indicated in Figure 2, the Bair Hugger device is not a necessary cause, but a causal factor that increases risk of deep joint infection by adding an additional causal mechanism.

With regard to the question of how much the Bair Hugger device increases risk, the observational evidence from the study by McGovern et al. represents the most salient quantitative estimate—an elevated odds ratio of 3.8. Calculating a commonly used epidemiological statistic, the attributable risk in the exposed ($RR-1/RR$), the estimate is $2.8/3.8$ or 74%. With this magnitude of excess risk, the Bair Hugger device would constitute a substantial contributing cause.

A handwritten signature in black ink, reading "Jonathan M. Samet", is positioned above a horizontal line.

Jonathan M. Samet, M.D., M.S.

Distinguished Professor and Flora L. Thornton Chair

Department of Preventive Medicine Keck School of Medicine of USC

Director, USC Institute for Global Health

University of Southern California

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Figure 1: Hypothetical Example of Three Sufficient Causes of Disease From: Rothman KJ, Greenland S. Causation and causal inference in epidemiology. Am J Public Health. 2005; 95 Suppl 1:S144-50.

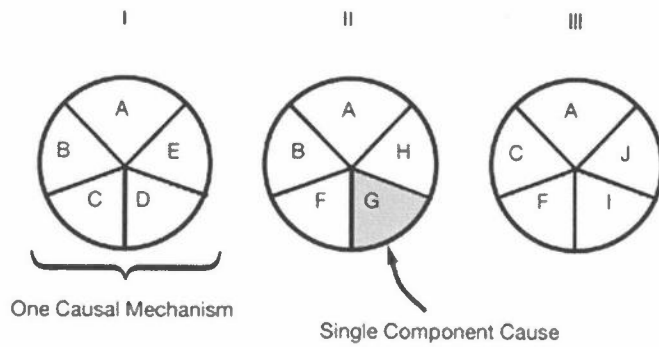
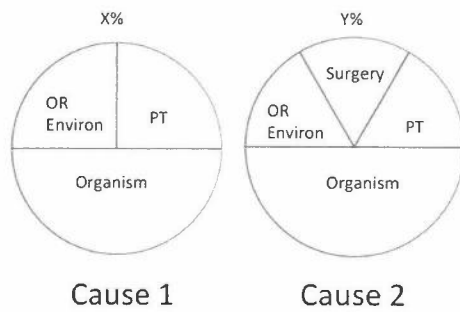


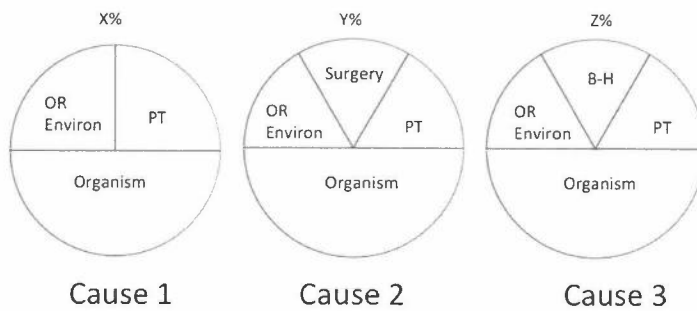
Figure 2: Adaptation of Sufficient Component Cause Model to Deep Joint Infection Risk

A: Causal Mechanisms for Deep Joint Infection without Bair-Hugger Devices



These causal pies are hypothetical and are not drawn to scale.
 OR Environ = Operating Room Environment; PT = Patient;
 Surgery = Surgical procedure factors

B: Causal Mechanisms for Deep Joint Infection with Bair-Hugger Devices



These causal pies are hypothetical and are not drawn to scale.
 OR Environ = Operating Room Environment; PT = Patient; B-H = Bair Hugger Device
 Surgery = Surgical procedure factors

Figure 3: Mechanisms by which the Bair Hugger Device Increases Risk for Deep Joint Infection

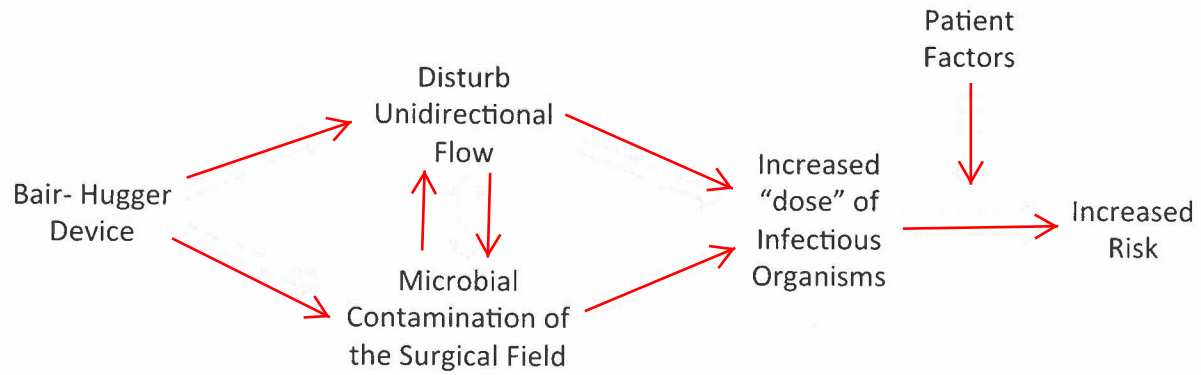


Table 1. Guidelines for causal inference. Data from the 1964 Smoking and Health: Report of the Advisory Committee to the Surgeon General and from Hill 1965

US Surgeon General Report's criteria	Hill's criteria
Consistency of association	Strength
Strength of association	Consistency
Specificity of association	Specificity
Temporal relationship of association	Temporality
Coherence of association	Biological gradient
	Coherence
	Experiment

Table 2. Studies comparing mean temperature differences of potential surgical site contamination with comparison of Bair Hugger device versus control

Reference	Indicator	Bair Hugger Device	Comparison	Ratio
Legg et al. 2012	Temperature difference (°C)	1.1°C	Radiant warming 0.4°C	$p < 0.001$
Desari et al. 2012	Temperature difference (°C)	Floor 0°C Table 0°C Head 0°C Shoulders 1.9°C Surgical site (abdomen) 3.8°C Knees 7.1°C	Hot Dog (an over-body conductive blanket) Floor 0°C Table 0°C Head 0°C Shoulders 1.8°C Surgical site (abdomen) 1.0°C Knees 3.9°C Inditherm (an under-body resistive mattress) Floor 0°C Table 0°C Head 0°C Shoulders 0.2°C Surgical site (abdomen) 0.1°C Knees 0.4°C	Hot Dog +2.73; $p < 0.001$ Inditherm +3.63; $p < 0.001$

Table 3. Studies comparing indicators of potential surgical site contamination with comparison of Bair Hugger device versus control

McGovern et al. 2011	Neutral-buoyancy detergent bubbles counted by photos	half drape 68 laid-down 3 full-drape 0	conductive warming half-drape 0 laid-down 0 full-drape 1	Infinite for half-drape and laid-down and 0 for full-drape
Legg et al. 2012	HandiLaz handheld particle counter over surgical site	0.3 microns mean=1038.2	0.3 microns 274.8 (no warming)	3.78 (p=0.0087)
Legg et al. 2013	0.3 micron glycerol particles measured over surgical site with HandiLaz particle counter	2.174x10 ⁶ /m ³	2x10 ³ /m ³ (no warming used)	2,174
Belani et al. 2013	Neutrally buoyant detergent bubbles counted by a sequence of 10 photographs taken at 10-second intervals per experimental run	Modeled estimate of 132.5	modeled estimate of 0.48 for conductive warming	276

Exhibit A

Curriculum Vitae / List of Publications

Jonathan Michael Samet

PERSONAL DATA

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EDUCATION AND TRAINING

A.B. 1966	Harvard College, Chemistry and Physics
M.D. 1970	University of Rochester School of Medicine and Dentistry
M.S. 1977	Harvard School of Public Health

Postdoctoral Training

1975-78	Research Fellow in Clinical Epidemiology, Channing Laboratory, Harvard Medical School, Boston, Massachusetts
1973-75	Resident in Medicine, University of New Mexico Affiliated Hospitals, Albuquerque, New Mexico
1970-71	Intern in Medicine, University of Kentucky Medical Center, Lexington, Kentucky

Licensure Formerly licensed in New Mexico, Maryland, Massachusetts

Certification Diplomate, National Board of Medical Examiners
Diplomate, American Board of Internal Medicine

Diplomate, American Board of Internal Medicine, Subspecialty of
Pulmonary Medicine

PROFESSIONAL EXPERIENCE

2016-	Director, Workforce Development and KL2 Program, Southern California Clinical and Translational Science Institute (SC CTSI)
2014-	Distinguished Professor, University of Southern California, Los Angeles, California
2010-2015	Director, Education, Career Development, and Ethics Program (ECDE), Southern California Clinical and Translational Science Institute (SC CTSI)
2008-	Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, California
2008-	Director, USC Institute for Global Health, University of Southern California, Los Angeles, California
2008-	Adjunct Professor, Department of Epidemiology, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland
1998-08	Director, Institute for Global Tobacco Control, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland
1995-08	Co-Director, Risk Sciences and Public Policy Institute, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland
1995-08	Secondary Appointment, Oncology Center, The Johns Hopkins University, Baltimore, Maryland
1994-08	Joint Appointment, Department of Medicine, School of Medicine, The Johns Hopkins University, Baltimore, Maryland
1994-08	Professor and Chairman, Department of Epidemiology, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland
1994-00	Co-Director, The Center for Epidemiology and Policy, Bloomberg School of Public Health, The Johns Hopkins University, Baltimore, Maryland
1994-96	Adjunct Scientist, Inhalation Toxicology Research Institute

1994-97	Clinical Research Professor, Department of Medicine, University of New Mexico, Health Sciences Center, Albuquerque, New Mexico
1986-94	Professor of Family, Community, and Emergency Medicine, University of New Mexico, Albuquerque, New Mexico
1986-94	Professor of Medicine, University of New Mexico, Albuquerque, New Mexico
1986-94	Chief, Pulmonary and Critical Care Division, Department of Medicine, University of New Mexico School of Medicine, Albuquerque, New Mexico
1985-86	Associate Professor of Family, Community, and Emergency Medicine, University of New Mexico, Albuquerque, New Mexico
1985-94	Chief, Pulmonary Division, University of New Mexico Hospital, Albuquerque, New Mexico
1982-86	Associate Professor of Medicine, University of New Mexico, Albuquerque, New Mexico
1980-94	Epidemiologist, New Mexico Tumor Registry, University of New Mexico, Cancer Research and Treatment Center, Albuquerque, New Mexico
1978-82	Assistant Professor of Medicine, University of New Mexico, Albuquerque, New Mexico
1978-83	Research Associate in Medicine, Harvard Medical School, Boston, Massachusetts
1975-78	Research Fellow in Clinical Epidemiology, Channing Laboratory, Harvard Medical School, Boston, Massachusetts
1974-75	Senior Resident in Medicine, University of New Mexico Affiliated Hospitals, Albuquerque, New Mexico
1973-74	Assistant Resident in Medicine, University of New Mexico Affiliated Hospitals, Albuquerque, New Mexico
1971-73	U.S. Army, Anesthesiologist at Gorgas Hospital, Balboa Heights, Canal Zone
1970-71	Intern in Medicine, University of Kentucky Medical Center, Lexington, Kentucky

PROFESSIONAL ACTIVITIES

Society Memberships

American Cancer Society

2010- Member, Cancer and the Environment Team

Society for Epidemiologic Research

1989-90 President

1988-91 Executive Committee

1988-89 President-Elect

American Thoracic Society

2007-08 Member, Task Force on Spirometry

2005-08 Program Committee, Environmental and Occupational Health Assembly

2005-06 Member, Environmental Health Policy Committee

1994-96 Program Committee, Behavioral Sciences Section

1992-95 Long Range Planning Committee, Environmental and Occupational Health Assembly

1987-88 Chairman, Workshop on Environmental Controls and Lung Disease

1987-88 Program Committee, Environmental and Occupational Health Assembly

1983-84 Chairman, Environmental and Occupational Health Assembly Annual Meeting Committee

1981-83 Secretary, Environmental and Occupational Health Assembly

1980-85 Program Committee, Environmental and Occupational Health Assembly

1979-82 Member, Steering Committee, EPA-American Lung Association Project, Physician Seminars on Health Effects of Air Pollution

New Mexico Thoracic Society

1984-85 President

1983-84 Vice-President

1982-83 Secretary-Treasurer

American College of Epidemiology, Fellow

2007-2010 Co-Chair, Policy Committee

2000-01 President

1999-00 President-Elect

1997-03 Member, Board of Directors

American Association for the Advancement of Science, Fellow

California Thoracic Society

International Society of Indoor Air Quality and Climate

Society for Research on Nicotine and Tobacco

Advisory Panels

- 2016 Chair, Gilbert W. Beebe Symposium on 30 Years after the Chernobyl Accident: Current and Future Studies on Radiation Health Effects
- 2016- Chair, Committee on Medical and Epidemiological Aspects of Air Pollution on US Government Employees and their Families, National Academies of Sciences, Engineering, and Medicine
- 2016- Member, Guideline Development Group, WHO Air Quality Guidelines
- 2016- Member, American Lung Association Scientific and Medical Editorial Review Panel
- 2015-2016 Chair, Incorporating 21st Century Science into Risk-Based Evaluations, National Research Council
- 2014- Member, Gulf Research Program Advisory Board, National Research Council
- 2013-2014 Chair, Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase II Pilot Planning Committee, National Research Council
- 2013 Chair, Working Group on Ambient Air Pollution, International Agency for Research on Cancer (IARC)
- 2013- Expert member, External Advisory Board, Mayo Clinic Lung Cancer SPORE
- 2013-2014 Executive Councilor, Radiation Effects Research Foundation
- 2012-2016 Chair, National Advisory Committee, Robert Wood Johnson Foundation Health & Society Scholars
- 2012-2014 Chair, Committee to Review the IRIS Process, National Research Council
- 2012-2013 Chair, Health Impact Assessment Academic Advisory Committee, California Air Resources Board
- 2012-2013 Vice-Executive Councilor, Radiation Effects Research Foundation
- 2012- Member, Board of Councilors, Radiation Effects Research Foundation

- 2012 Chair, Workshop Planning Committee, Improving Science in the Administrative Process: A Workshop. Committee on Science Technology and Law, the National Academies
- 2011-2016 Member, National Cancer Advisory Board
- 2011 Chair, Working Group on Non-Ionizing Radiation: Radiofrequency Electromagnetic Fields, International Agency for Research on Cancer (IARC)
- 2011-2012 Member, Board of Directors, Radiation Effects Research Foundation
- 2010-2014 Chair, Tobacco Products Scientific Advisory Committee, Food and Drug Administration
- 2010-2013 Chair, Committee to Develop a Research Strategy for Environmental Health and Safety Aspects of Engineered Nanomaterials, National Research Council
- 2010-2011 Chair, Committee to Review the Draft IRIS Assessment on Formaldehyde, National Research Council
- 2010-2012 National Advisory Committee, Robert Wood Johnson Foundation Health & Society Scholars
- 2010-2012 Chair, Interest Group on Environmental and Occupational Health and Toxicology, Institute of Medicine
- 2010-2013 Member, Scientific Advisory Committee of CanCOLD
- 2009-2010 Chair, Health Impact Assessment Academic Advisory Committee, California Air Resources Board
- 2009-2010 Member, Scientific Advisory Board for the National Heart, Lung, and Blood Institute (NHLBI) Global Health Initiative in Partnership with the UnitedHealth Chronic Disease Initiative Program
- 2009- Chair, Centre Advisory Board, MRC-HPA Centre for Environment and Health
- 2009-2010 Member, Planning Committee, Interest Group on Environmental and Occupational Health, Toxicology, Institute of Medicine
- 2008-2012 Chairman, Clean Air Scientific Advisory Committee, Science Advisory Board, U. S. Environmental Protection Agency

- 2008-2010 Co-Chair, Committee on Cancer and the Environment, American Cancer Society
- 2008-2012 Member, Science Advisory Board, U.S. Environmental Protection Agency
- 2007-2009 Member, Scientific Advisory Committee, World Trade Center Medical Programs at Mount Sinai School of Medicine
- 2007-2008 Member, Clean Air Scientific Advisory Committee, Science Advisory Board, U. S. Environmental Protection Agency
- 2006-2014 Chair, Scientific Advisory Committee, Centre for Research in Environmental Epidemiology (CREAL) Barcelona, Spain
- 2006-2007 Chairman, Committee on Evaluation of the VA's Presumptive Disability Decision-Making Process (PDDM), Institute of Medicine
- 2006-2009 Member, Executive Committee, Tyler Prize for Environmental Achievement
- 2005-2007 Member, Guideline Project Committee (GPC) 29, American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)
- 2004-2009 Member, Global Tobacco Advisory Board, Pfizer, Inc.
- 2004-2006 Chairman, Committee on Asbestos: Selected Health Effects, Institute of Medicine
- 2004-2010 Member, Advisory Board of the Centre for Emerging Infectious Diseases, The Chinese University of Hong Kong
- 2004- Member, Advisory Committee for the University of California, San Francisco Center for Tobacco Control Research and Education
- 2003-2008 Member, Advisory Board for the Clinical Research Curriculum Award, University of Maryland School of Medicine
- 2003-2008 Member, Environmental Factors and Cancer Advisory Committee, American Cancer Society
- 2003-2009 Chairman, Board on Environmental Studies and Toxicology, National Research Council
- 2003-2010 Member, Science, Technology, and Law Panel, National Research Council
- 2003-2010 Member, Scientific Advisory Board, R. Samuel McLaughlin Centre for

Population Health Risk Assessment, University of Ottawa

- 2002-2006 Member, External Scientific Advisory Board, Cancer Research and Treatment Center, University of New Mexico
- 2002-2008 Chairman, Scientific Advisory Committee, Genetics, Air Pollution and Respiratory Effects in Children and Young Adults project, University of Southern California
- 2002- Member, Scientific Advisory Committee, American Lung Association
- 2002-2003 Member, Board on Environmental Studies and Toxicology, National Research Council
- 2002-2003 Member, The National Children's Study Advisory Committee, National Institutes of Health
- 2001-2002 Expert Consultant, Exubera Global Development Team, Pfizer Inc.
- 2001-2007 Member, Epidemiology Review Board, E. I. duPont de Nemours and Company, Inc.
- 2001-2006 Member, Awards Assembly, General Motors Cancer Research Foundation
- 2002 Chairman, Working Group on Smoking and Involuntary Smoking, International Agency for Research on Cancer, World Health Organization
- 2002-2004 Member, Scientific Advisory Committee of the Systematic Review of Health Aspects of Air Quality in Europe Project, World Health Organization
- 2000-2001 Chairman, Peer Review Panel on the State of the Science Concerning *Pfiesteria*, Centers for Disease Control and Prevention
- 2000-2002 Member, Research Advisory Board of the Meyer Center, Johns Hopkins University School of Medicine
- 1999-2004 Chairman, External Advisory Committee, Southern California Particle Center and Supersite, UCLA
- 1999-2005 Member, Scientific Advisory Committee, Northwest Research Center for Particulate Air Pollution and Health, University of Washington
- 1999-2005 Consultant, Clean Air Scientific Advisory Committee, Science Advisory

Board, U. S. Environmental Protection Agency

- 1998-2001 Member and Chairman (2001), Charles S. Mott Selection Committee of the General Motors Cancer Research Foundation
- 1998-2004 Chairman, Committee on Research Priorities for Airborne Particulate Matter, National Research Council
- 1998-2006 Member, Research Committee, Health Effects Institute
- 1997-2002 Member, Maryland Air Quality Control Advisory Council, Maryland Department of the Environment
- 1996-2000 Chairman, External Advisory Committee, NIEHS Center, University of Southern California
- 1996-2003 Member, Board of Directors, Radiation Effects Research Foundation
- 1996-2008 Member, National Council on Radiation Protection and Measurements
- 1995-1999 Member, Board of Scientific Counselors, National Cancer Institute
- 1995-1997 Chairman, Scientific Advisory Committee, Iowa Persian Gulf Project, University of Iowa
- 1995-1996 Consultant, Clean Air Scientific Advisory Committee, Science Advisory Board, U.S. Environmental Protection Agency
- 1994-2008 Member, Board of Overseers, American Journal of Epidemiology
- 1995-2004 Member, National Advisory Council for the National Jewish Center for Immunology & Respiratory Medicine
- 1994-1998 Chairman, Biological Effects of Ionizing Radiation (BEIR) VI Committee, Phase II, National Research Council
- 1993-1995 Member, WIPP Subcommittee, National Advisory Council on Environmental Policy & Technology (NACEPT), U.S. Environmental Protection Agency
- 1992-1998 Member, Respiratory Advisory Board, ASTRA
- 1992-1994 Chairman, Biological Effects of Ionizing Radiation (BEIR) VI Committee, Phase I, National Research Council
- 1992-1998 Member, Commission on Life Sciences, National Research Council

- 1992-1998 Member, SSPC 62, American Society of Heating, Refrigeration, and Air-Conditioning Engineers
- 1991-1996 Task Force on Pneumoconioses, American College of Radiology
- 1991 Member, Fourth Task Force for Research Planning in Environmental Health Science, National Institute of Environmental Health Sciences
- 1991-1994 Pulmonary Disease Advisory Committee, Division of Lung Diseases, National Heart, Lung, and Blood Institute
- 1991-1997 Member, Board of Radiation Effects Research, National Research Council
- 1990-1994 Chairman, Research Oversight Committee, Health Effects Institute-Asbestos Research
- 1989-1991 Chairman, Panel on Dosimetric Assumptions Affecting the Application of BEIR IV Risk Estimates, National Research Council
- 1989-1997 Member, National Air Conservation Commission, American Lung Association
- 1989-1990 Member, Health Subcommittee, Relative Risk Reduction Project of the Science Advisory Board, U.S. Environmental Protection Agency
- 1989-1991 Member, External Advisory Committee, Northern California Cancer Center
- 1988-1994 Member, Radon Task Group, Office of Health and Environmental Research, U.S. Department of Energy
- 1987-1995 Member, Indoor Air Quality and Total Human Exposure Committee, Science Advisory Board, U.S. Environmental Protection Agency
- 1987-1990 Member, Mine Health Research Advisory Committee, Centers for Disease Control
- 1987 Member, Working Group on Man-made Mineral Fibres and Radon, International Agency for Research on Cancer, World Health Organization
- 1986-1987 Member, Oversight Panel, University of California, Davis, Review of the Occupational Health System of the Semiconductor Industry Association
- 1986-1989 Member, Task Group 9 of Scientific Committee 57, "Lung Cancer Risk", National Council on Radiation Protection and Measurements

- 1985-1987 Member, Biological Effects of Ionizing Radiation (BEIR) IV-Alpha Committee, National Research Council, National Academy of Sciences
- 1985 Member, Working Group on Tobacco Smoking, International Agency for Research on Cancer, World Health Organization
- 1984-1992 Member, Monitoring Board, CARDIA Study, National Heart, Lung, and Blood Institute
- 1984-1987 Member, National Air Conservation Commission, American Lung Association
- 1984-1986 Member, Science Advisory Board, Acid Deposition Research Program Province of Alberta, Canada

EDITORIAL ACTIVITIES

Peer-Review Activities

- 2002-2004 Chairman, Epidemiology of Cancer Study Section, National Institutes of Health
- 1986 Member, Parent Review Committee, SCOR Program, Division of Lung Diseases, National Heart, Lung, and Blood Institute
- 1984-1989 Member, U.S. Environmental Protection Agency Research Review Panel
- 1981-1984 Member, Epidemiology and Disease Control Study Section, National Institutes of Health

Editorial Board Membership

- 2014- Associate Editor, Population Health Metrics
- 2014-2015 Section Editor, Current Environmental Health Reports
- 2013- Honorary Editor-in-Chief, World Journal of Tobacco or Health
- 2012- Member, Editorial Board, Carcinogenesis
- 2010-2014 Member, Editorial Board, BMC Public Health

- 2010- Member, Korean Society for Preventive Medicine, Journal of Preventive Medicine and Public Health
- 2008- Editorial Board Member, American Journal of Respiratory and Critical Care Medicine
- 2008-2011 Member, Editorial Board, Preventive Medicine
- 2007- Co-Editor-in-Chief, Air Quality, Atmosphere and Health
- 2005-2008 Consulting Editor, Archives of Environmental Health
- 2005-2014 Member, Board of Consulting Editors, MEDICINE
- 2004- U.S. Epidemiology Section Head, Faculty of 1000 Medicine Reports
- 2004-2007 Editorial Advisory Board, European Journal of Epidemiology
- 2003-2008 Member, International Editorial Advisory Board, Hong Kong Medical Journal
- 2002- Editorial Board, Population Health Metrics
- 2001-2007 Editor, Epidemiology
- 1994-2002 Editor, Epidemiologic Reviews
- 1992-1998 Editor, American Journal of Epidemiology
- 1991-2001 Associate Editor, Tobacco Control: An International Journal
- 1991-1992 Editor, pro tem, American Journal of Epidemiology
- 1989-1994 Associate Editor, American Review of Respiratory Disease
- 1998-2000 Editorial Board, Journal of Environmental Medicine
- 1997- Editorial Board, American Journal of Medicine
- 1997-2009, Editorial Board, American Journal of Respiratory and Critical Care Medicine
2013-
- 1996- Editorial Committee, Salud Pública de México
- 1991-2009 Associate Editor, Cancer Epidemiology, Biomarkers and Prevention

1988-2000 Editorial Board, Epidemiology

1988-1989 Editorial Board, American Review of Respiratory Disease

1986-1991 Associate Editor, American Journal of Epidemiology

1982-1988 Editorial Board, Annals of Sports Medicine

HONORS AND AWARDS

Doctorate Honoris Causae, Instituto Nacional de Salud Pública (INSP), Mexico 2017

Fellow, Society for Research on Nicotine and Tobacco, 2017

Public Health Leadership Award, CEASE Program, Morgan State University, 2016

Fries Prize for Improving Health, CDC Foundation, 2016

Woodson Lecture, University of Louisville, 2016

David M. Rall Award, National Academy of Medicine, 2015

Abraham Lilienfeld Award, American College of Epidemiology, 2015

Luther Terry Award for Distinguished Career, American Cancer Society, 2015

Harold and Marilyn Menkes Memorial Lecture, Johns Hopkins Bloomberg School of Public Health, 2015

B.J. Kennedy Lecture in Medical Oncology, University of Minnesota, 2014

Research Award, University of New Mexico School of Medicine 50th Anniversary, 2014

Distinguished Professor, University of Southern California, 2014

Phi Kappa Phi Honor Society 2014

David Bates Memorial Lecture, 2013

The Edward Livingston Trudeau Medal, American Thoracic Society/American Lung Association, 2013

Robert Zweig Memorial Award, South Coast Air Quality Management District, 2011

The Robert S. Gordon, Jr. Lecture in Epidemiology, National Institutes of Health, 2011

Doll-Wynder Award, Society for Nicotine and Tobacco Research, 2011

The Alton Ochsner Award Relating Smoking and Health, 2008

The Golden Honorary Award of the "Health Promotion" Foundation, Poland, 2008

World No Tobacco Day 2007 Award, World Health Organization

Breath of Life Award, American Lung Association of Maryland, 2006

Distinguished Alumnus Award, University of Rochester School of Medicine and Dentistry, 2006

Surgeon General's Medallion, 2006

Global Smokefree Partnership Award, 2006

Public Service Award, American Thoracic Society, 2006

John Goldsmith Award for Outstanding Contributions to Environmental Epidemiology, International Society for Environmental Epidemiology, 2005

Prince Mahidol Award in Public Health, Prince Mahidol Award Foundation, 2005

Visiting Scholar Award, Division of Cancer Epidemiology and Genetics, National Cancer Institute, 2004

George Wills Comstock, M.D., Award, American Lung Association of Maryland, 2003

Dr. William Cahan Distinguished Professor Award, Flight Attendant Medical Research Institute, 2003

The 136th Cutter Lecture on Preventive Medicine, Harvard School of Public Health, 2002

Honorary Fellowship Award, American College of Chest Physicians, 2002

Joseph W. Cullen Memorial Award, American Society of Preventive Oncology, 2002

The Fourteenth Richard T. Cushing, MD Medical Lecture Program, American Lung Association of Minnesota, 2001

Alumni Award of Merit, Harvard School of Public Health, 2001

Jacob I. and Irene B. Fabrikant Professor in Health, Risk, and Society, Bloomberg School of Public Health, Johns Hopkins University, 2000

Institute of Medicine, National Academy of Sciences, 1997

Fellow, American Association for the Advancement of Science, 1996

Award for Excellence in Environmental Health Research, The Lovelace Institute, 1996

Delta Omega Honorary Society in Public Health, Alpha Chapter, 1995

American Epidemiological Society, 1992

Surgeon General's Medallion, 1990

Western Association of Physicians, 1990

Annual Research Lecturer, University of New Mexico, 1990

Presidential Professor in Medicine, University of New Mexico, 1989-1994

American Society for Clinical Investigation, 1989

Alpha Omega Alpha, 1989

Ralph C. Williams, Jr., M.D., Award for Research Contributions to the Department of Medicine, University of New Mexico, 1987

Presidential Lecturer in Medicine, University of New Mexico, 1986-1988

Clinton P. Anderson Award, American Lung Association of New Mexico, 1986

Research Career Development Award, Division of Lung Diseases, NHLBI, 1981-1986

BOOKS AND MONOGRAPHS

1. Samet, JM (Consulting Scientific Editor). The Health Consequences of Smoking: Cancer and Chronic Lung Disease in the Workplace. Rockville, U. S. Department of Health and Human Services **1985**; 542 pages.
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PROCEEDINGS OF MEETINGS

1. Samet JM, Morgan MV, Buechley RW, et al. Studies of Grants, New Mexico, uranium miners. Current status. In: Gomez M (ed). International Conference on Radiation Hazards in Mining: Control, Measurements, and Medical Aspects. American Institute of Mining, Metallurgical, and Petroleum Engineers, New York, **1981**; 680-684.
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Exhibit B

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Exhibit C

Materials Considered

Deposition Transcripts and Exhibits in Johnson v. 3M

1. Gary Maharaj August 19, 2015 Deposition Transcript and Exhibits 1-19
2. Gary Hansen August 27, 2015 Deposition Transcript and Exhibits 1-40
3. Daniel Sessler November 20, 2015 Deposition Transcript and Exhibits 1-18

Deposition Transcripts and Exhibits in Walton v. 3M

1. Gary Hansen February 11, 2015 Deposition Transcript and Exhibits 1-17
2. Gary Maharaj February 19, 2015 Deposition Transcript and Exhibits 65-81
3. Daniel Sessler May 27, 2015 Deposition Transcript and Exhibits 1-34
4. Daniel Sessler July 9, 2015 Deposition Transcript and Exhibits 35-44

Deposition Transcripts and Exhibits in MDL

1. Kumar Belani September 7, 2016 Final Deposition Transcript
2. Mark Litchy September 28, 2016 Final Deposition Transcript
3. Robert Gauthier October 4, 2016 Final Deposition Transcript
4. Mark Albrecht October 7, 2016 Final Deposition Transcript
5. Gary Hansen November 2, 2016 Final Deposition Transcript and Exhibits 1-27
6. Al Van Duren November 7, 2016 Final Deposition Transcript and Exhibits 46-78
7. Mark Albrecht November 12, 2016 Final Deposition Transcript
8. Christopher Nachtsheim Nov. 29, 2016 Deposition Transcript and Exhibits 1-30
9. Andrew Legg December 1, 2016 Final Deposition Transcript
10. Michael Reed December 4, 2016 Final Deposition Transcript and Exhibits 1-13
11. Andrew Hamer December 4, 2016 Final Deposition Transcript
12. David Leaper December 8, 2016 Final Deposition Transcript
13. Robert Gauthier December 15, 2016 Final Deposition Transcript
14. Michelle Hulse-Stevens Dec. 19, 2016 Deposition Transcript and Exhibits 204-25
15. Paul McGovern January 4, 2017 Deposition Transcript
16. Paul McGovern January 5, 2017 Deposition Transcript and Exhibits 1-27
17. Daniel Sessler January 11, 2017 Deposition Transcript and Exhibits 226-36
18. Andrea Kurz January 12, 2017 Deposition Transcript and Exhibits 237-47
19. 30(b)(6) Representative March 7, 2017 Deposition Transcript and Exhibits 350-51

Defendant's Expert Reports in Walton v. 3M

1. Joseph Solomkin Expert Report
2. Richard Wenzel Expert Report

Plaintiff's Expert Reports in Walton v. 3M

1. Yadin David Expert Report
2. Kenneth Diller Expert Report
3. Paul Edelson Expert Report
4. Michael Freeman Expert Report

Plaintiffs' Expert Reports in MDL

1. Said Elghobashi Expert Report
2. William Jarvis Expert Report

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3. 3MBH00001581
4. 3MBH00001582
5. 3MBH00001583-87
6. 3MBH00025739
7. 3MBH00041013
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9. 3MBH00050932-33
10. 3MBH00053034-36
11. 3MBH00054358-60
12. 3MBH00105349
13. 3MBH00107855
14. 3MBH00110370-71
15. 3MBH00111871-72
16. 3MBH00119574-76
17. 3MBH00123460-62
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19. 3MBH00130834-36
20. 3MBH00130837-41
21. 3MBH00130843
22. 3MBH00131560
23. 3MBH00133607-22
24. 3MBH00136547
25. 3MBH00508771-78
26. 3MBH00540276-78
27. 3MBH00551778-82
28. 3MBH00561641-43
29. 3MBH00561646-49
30. 3MBH00576839
31. 3MBH00597741-47

Third-Party Production Documents

1. Albrecht_0000274-79
2. Albrecht_0000280-83
3. Albrecht_0001622
4. Albrecht_0001667-71
5. Albrecht_0002079-86
6. Albrecht_0002227-34
7. Albrecht_0002236-37
8. Albrecht_0002262-71
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10. Albrecht_0002275-78
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Miscellaneous Documents

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- 2. 3M Bair Hugger Research Compendium
- 3. Albrecht Data:
<https://github.com/albre116/LogisticRegressionAugustine/find/master>
- 4. Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection
- 5. KHN Article: Deadly Infections Linked to Heart Surgery Device Highlight Holes in FDA Monitoring
- 6. National Academies of Sciences, Engineering, and Medicine Report
- 7. Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee, November 5-6, 2015, Record of Proceedings.
- 8. Centers for Disease Control and Prevention, Non-tuberculous Mycobacterium (NTM) Infections and Heater-Cooler Devices: Interim Practical Guidance, October 27, 2015.
- 9. Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee, March 31, 2016, Record of Proceedings.

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Exhibit D

Statement of Compensation

In this multidistrict litigation involving the Bair Hugger forced-air warming device, I have provided consultation services at a reasonable rate of \$600 USD per hour through a contract between Ciresi Conlin LLP and the University of Southern California. These services include but are not limited to reviewing materials, conducting meetings, and drafting the expert report pertaining to this litigation. I provided these services on behalf of the Department of Preventive Medicine at the Keck School of Medicine of the University of Southern California, 2001 N. Soto Street, Los Angeles, California, 90089-9239. All invoices regarding said services were invoiced by and paid to the Keck School of Medicine.